



Integrated Research Software
Presentation



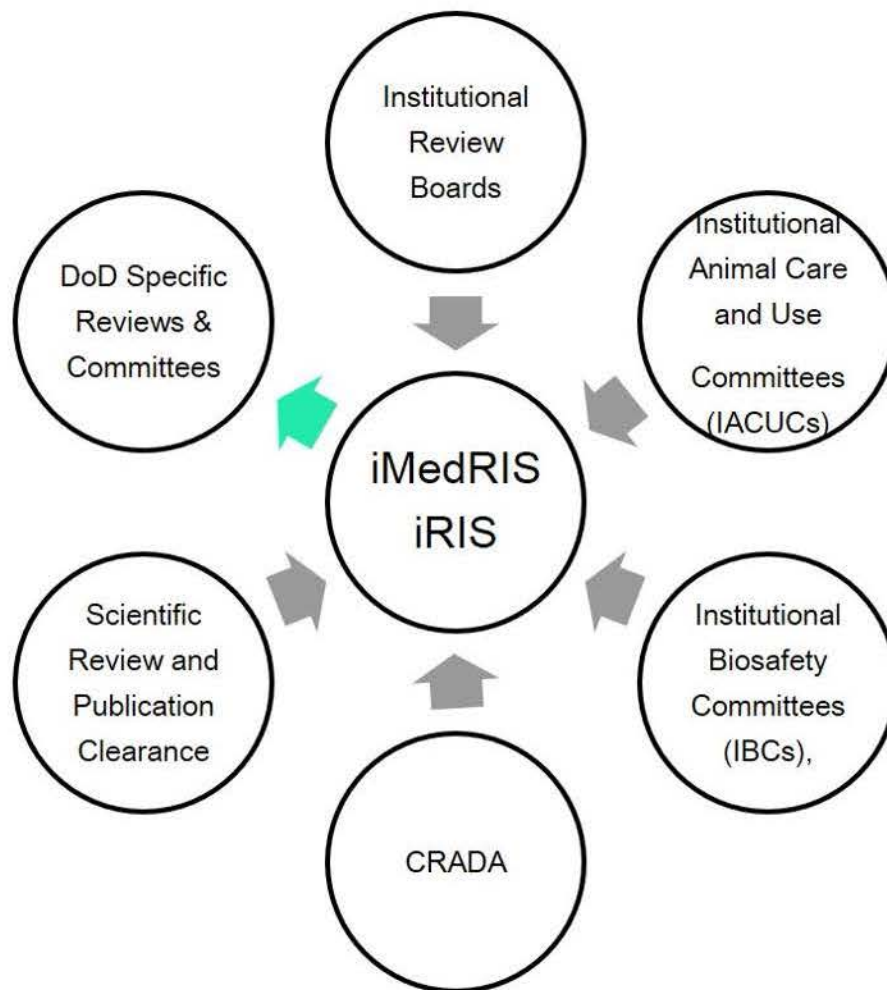


Company Profile

- i Incorporated in 2001**
- i First customer “Live” in 2002**
- i Located in Redlands, CA**
- i Equal Opportunity Employer**
- i Fully developed Integrated Research Management System**



Integrated Research Information Software



- i IRB Assistant**
- i IBC Assistant**
- i IACUC Assistant**
- i Radiation Safety Assistant**
- i Scientific Review Assistant**




- i Integrated Framework System**
- i Adaptable To Business Logic**
- i Role Based User Access**
- i Wizard & Non-Wizard Forms**
- i Create Your Specific Workflow**
- i Unlimited Boards & Committees**
- i Customizable Configuration Lists**
- i Print Friendly Documents**

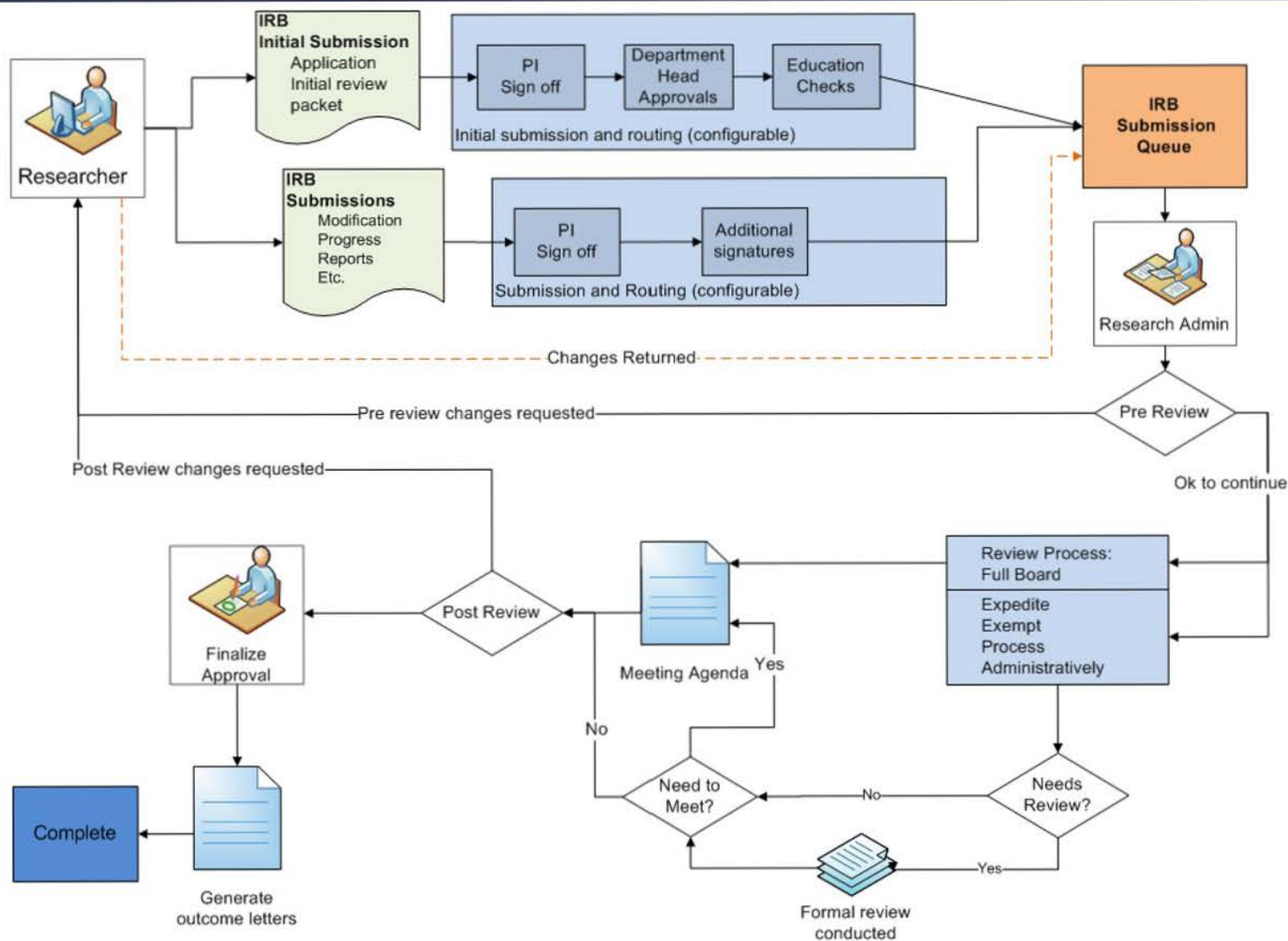



- i Active Forum**
- i Annual User Group Conferences**

- ❶ **Submit studies electronically to the compliance office for review**
- ❷ **Review Protocol documents Online**
- ❸ **Correspond directly with researchers and committees electronically**
- ❹ **Electronically create and modify review board documents**
- ❺ **Approve consent or HIPAA forms**
- ❻ **Automated Review Board documents**
- ❼ **Electronic Agendas**
- ❽ **Automatically record attendance**
- ❾ **Capture votes**



- 
- i Access production study data**
 - i Generate and Stamp outcome letters**
 - i Automatic generation of Meeting Minutes**
 - i Generate Pre-canned and Customizable Reports**
 - i Detailed and Easy Review Response / Corrections**
 - i Submission Stipulations linking to Forms/Documents**
 - i Unlimited rounds between Researcher / Board – Committees**
 - i Automatic generation of tasks and email notifications**





Account: Principal investigator
Site: Healthcare System - Healthcare System

Home Logout ? Help

- My Assistant
- Study Assistant
- Change your default Site

Welcome Principal investigator

Study Assistant

Add a New Study

My Protocols

Find a Study

Below are your incomplete Study tasks:

Waiting Submission	1
Submission Routing Signoff	1



iRIS

Powered by IMedRIS

Account: Principal investigator
Site: Healthcare System - Healthc

● My Assistant

● Study Assistant

 Change your default Site

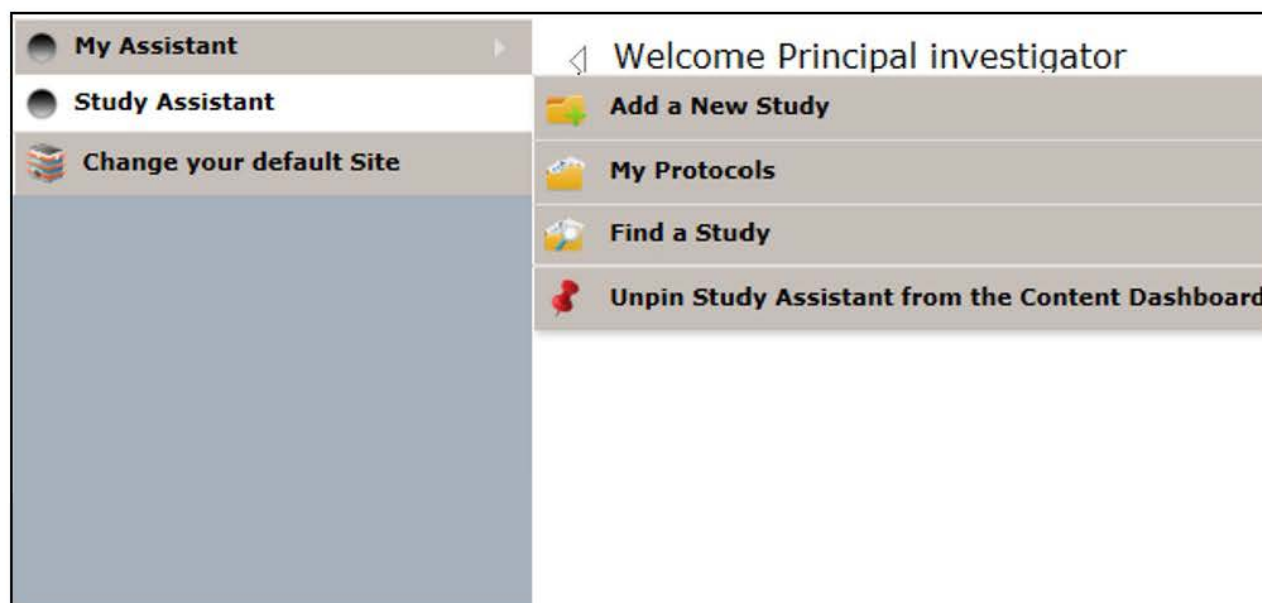
 My Account Information

 Announcements

 Operating Procedures


- i User demographics and file uploads
- i System wide announcements to iRIS user community
- i Existing policies and procedures available to user community









Study Assistant Menu Group




“Unpin Study Assistant from the Content Dashboard” This allows a user to add or remove a menu group from their home page. If the menu group is unpinned the functional buttons listed above will only be available through this menu.

Board Members view of dashboard area on login

IRB Assistant 

 Find a Study
  Reviewer Assignment
  Reviewer Dashboard
  Meeting Agenda
  Meeting Minutes
  Meeting Availability
  Letter Signoff
  Correspondence

 Reports

Below are your incomplete IRB tasks:



Reviewer Assignment

 Open Dashboard












1

1 task(s) found...

1 - 1


Open	Principal Investigator	IRB Number	Study Alias	Study Status	Submission Form Name	Submission Date	Review Process	IRB Initial Approval	Expiration	Received
	Gatekeeper Rounds Test 2.17.2015									
	Randy Minarik		Gatekeeper Rounds Test 2.17.2015	Pending - Submitted for Initial Review	Submission Response for Initial Review Submission Form	02/17/2015	Administrative			04/02/2015























Board Members view of left menu on home page

 IRB Assistant	 Find a Study
 Change your review board	 Reviewer Assignment
 Change your default Site	 Reviewer Dashboard
	 Meeting Management ▶
	 Correspondence & Notifications ▶
	 Letter Signoff
	 Reports
	 Unpin Project Assistant from the Content Dashboard

Board coordinators view of dashboard area on login

IRB Assistant 

Select the Committee: 

 Find a Study	 Submissions	 Analyst Dashboard	 Reviewer Assignment	 Reviewer Dashboard	 Meeting Agenda	 Meeting Minutes	 Meeting Manager	 Meeting Availability
 Continuing Review Monitor	 Outstanding Responses	 Stipulations Tracking	 Letter Signoff	 Invoice History	 Correspondence	 Drug/Device Email	 Audit System Notifications	 Grant User Access & Define Roles
 User Training	 Reports	 Submission Forms	 Review Board Administration					

Below are your incomplete IRB tasks:

	Analyst Assignment		Open Dashboard	1
	Submission Reviewers Complete			1

Once you find the study you are looking for, you can click the icon in the **Open** column to open the study record.

IRB - Find a Study

Back

Find a Study Filters

Display Projects by: IRB Number

Study Number:

Sponsor:

Active

Principal

Investigator:

Department:

Study Status: Open

Study Classification: All

Reference Number:

IRB Number:

IRB Expiration Date:

-

Advanced Find Options

Reset Find Options

Find ...

1 result(s) found... 1 - 1

IRB Number: GH-2015-22		Submissions		Back								
PI: Investigator, Susan												
Study Status: Open	IRB Number : GH-2015-22	Study Title : Treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) With Atomoxetine in Young Adults and Its Effects on Functional Outcomes										
IRB Expiration Date: 12/31/2015												
<div>Submissions</div> <div>Study Management</div>												
Protocol Items <ul style="list-style-type: none"> <input type="radio"/> Study Application <input type="radio"/> Informed Consent <input type="radio"/> Other Study Documents 		<ul style="list-style-type: none"> <input type="radio"/> Submissions History <input type="radio"/> Study Correspondence 										
Initial Review <div>Submissions</div>		<table border="1"> <thead> <tr> <th>Track Location</th> <th>Ref Number</th> <th>Request Type</th> <th>Process Submission</th> </tr> </thead> <tbody> <tr> <td colspan="4">There are no outstanding submissions.</td> </tr> </tbody> </table>			Track Location	Ref Number	Request Type	Process Submission	There are no outstanding submissions.			
Track Location	Ref Number	Request Type	Process Submission									
There are no outstanding submissions.												

Meeting Agenda allows you to view information related to a specific meeting date. You can access past and future meetings from this area.

IRB - Review Board Meeting Agenda

Back

Agenda State: Draft

Reviewer Notifications: Disabled

◀ 06/01/2014 ▶

Submission Review validation

Save Changes

Items to be Reviewed at Committee 1 Meeting :

Meeting Attendance

Call to Order

Old Business

New Business

Miscellaneous

Closing Comments

Meeting Motions

Review Documents

View File	Title
No documents have been associated with this agenda	

Meeting Start Time:

AM ▼

Meeting End Time:

AM ▼

Meeting Chair:

--none-- ▼

Initial Reviews - 0 Submissions

0 Items for review in this category.

The **Meeting Availability** tool allows a user to indicate their availability for any future board meetings.

Meeting Availability
 **Back**

 **Save the availability**

Committee 1 Committee Meeting: 07/15/2015 ▶

Members Name	Will be Present	Will Not be Present	Available for Review
Administrator	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Member, Edward	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Member, Jane	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Member, Joe	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Member, Lucy	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Member, Peter	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No
Consultant/Ad Hoc Reviewers Name	Will be Present	Will Not be Present	Available for Review
Member, Jane	<input type="radio"/>	<input type="radio"/> <small>No Response indicates presence at this meeting</small>	<input checked="" type="radio"/> Yes <input type="radio"/> No

Compare Tool

If there is more than one version of the application, there will be a folder icon in the **Show Rev** column. Note that the number of versions is also listed in the **Application Type** column, after the name of the application.



1 result(s) found...

	Show Rev.	Edit/View	Application Type	Approved?	Approval Date	Created By	Date Created	Modified by	Date Modified	Create a Revised Application
			Study Application (Version 1.1)	Yes	02/24/2014	Mary Jane Coordinator	02-13-2014 14:11	Mary Jane Coordinator	02-24-2014 15:00	
			Study Application (Version 1.0)	No		Mary Jane Coordinator	02-12-2014 16:21	Susan M. Investigator	02-12-2014 16:21	

close

Study Application

Version: 1.0
Mary Jane Coordinator

Version: 1.1
Mary Jane Coordinator

1 Not Defined in Version 1.0

Section 4 - Section 200
Q 4 - Sub form attach:

No form has been associated.

2 Section 6 - Section 300
Q 1 - Human Subjects Training is a requirement for approval. Have you and your research team members completed Human Subjects Trainin ...

Section 6 - Section 300
Q 1 - Human Subjects Training is a requirement for approval. Have you and your research team members completed Human Subjects Trainin ...

o Yes o No

o Yes ~~o No~~ No

3 Section 6 - Section 300
Q 2 - Is this study or any part of this study contributing to a dissertation or thesis?

Section 6 - Section 300
Q 2 - Is this study or any part of this study contributing to a dissertation or thesis?

o Yes o No

o Yes ~~o No~~ No

4 Section 12 - Study management Links
Q 1 -

Section 12 - Study management Links
Q 1 -

Order
Number

Criteria

1

In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.

Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD), psychosis, bipolar illness, severe obsessive compulsive disorder, severe depressive or severe anxiety disorder or other

Order
Number

Criteria

1

In the opinion of the investigator, the subject is significantly underweight [e.g., Body Mass Index (BMI) < 18.5] or morbidly obese.

Has any comorbid psychiatric diagnosis with significant symptoms such as any severe comorbid Axis II disorders or severe Axis I disorders including Post Traumatic Stress Disorder (PTSD),

Submissions - This area links to different submission forms that can be sent to a review board as needed. The list of forms here will change depending on the forms setup in your system. You can create and submit a form any time by clicking on the link for the form.

IRB Number: **GH-2015-25**
 PI: Investigator, Susan

Submissions
[Back](#)

Study Status: **Open**

IRB Number : **GH-2015-25**

Study Title : A Phase III, Randomized, Double-Blind, Multi-Center, Placebo-Controlled, Parallel-Group, Forced Dose Titration, Safety and Efficacy Study of NRP104 in Adults With Attention-Deficit Hyperactivity Disorder (ADHD)

IRB Expiration Date: 06/16/2016

Submissions

Study Management

Subject Management

Protocol Items

Protocol Items

- Study Application
- Informed Consent
- Other Study Documents

Initial Review

Submissions

- Initial Review Submission Packet


IRB Items

Forms

- Continuing Review Submission Form
- Amendment Form
- Adverse Event
- Study Closure Form











Submissions History

 Study Correspondence


Outstanding Submission(s)

Track Location	Ref Number	Request Type	Process Submission
There are no outstanding submissions.			

Track Location – Once a form has been submitted into the workflow, you can track the location of the submission using our “Submission History” tab. New submissions will also present a “tracking slip” once they have been electronically submitted to your IRB.

IRB Number: GH-2015-25		Workflow - Submission Tracking		Back
PI: Investigator, Susan		Print Friendly		
Status	View Details	Date Received / Date Completed		Event Description
		07/01/2015 02:40 PM PDT		IRB received the submission
		07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Mary Jane Coordinator as Clinical Research Coordinator review and apply signoff
	 Routing Assignment List	07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Assign Department Personnel for Signoff
		07/01/2015 02:40 PM PDT 07/01/2015 02:40 PM PDT		Amendment Form is waiting to be submitted

Questions & Answers

